## **Genomics RFA FAQs**

What is the allowed time frame for the Centers to be operational?

The award must be initiated within 9 months of approval by our governing board, the ICOC, unless CIRM's President grants an extension based upon compelling justification of the need for additional time. Given the timeline in the RFA, ICOC approval is expected in Spring 2013, a likely operational date would be January 2014. CIRM is concerned with the urgency of its mission and views the timely initiation of these programs as extremely important.

For the collaborative funding part of the program, when the Center is collaborating with an
outside investigator, should the CIRM funds be used to pay for activities that the Center
conducts as its in-kind contribution to the project? And/or should the Center be using the funds
to make sub-awards that fund the work of the outside collaborator?

The collaborative research part of the program is a key aspect of the award, and as such, we have set a minimum of 30% of the budget for this activity. The goal of this component is to provide stem cell scientists throughout California with access to state-of-the-art genomics and bioinformatics technologies and expertise and assistance in experimental design and genomics data analysis. We are leaving the question of how to organize the collaborative funding activities rather open and expecting applicants to propose their own strategies. Our reviewers will then judge whether the proposed policies provide appropriate access and best serve the goal of the RFA, to make genomics approaches available to the California stem cell research community. Having said that, CIRM does not expect collaborators (in projects accepted by a Center's Collaborative Resources Committee) to have to pay for use of center resources (that is one of the key purposes of the collaborative funds). So, the use of some collaborative funds for "in kind" services at the Genomics Center would be expected.

Center Award applicants should propose plans for how collaborative funds would be used outside of the Center. CIRM considers it acceptable for collaborative funds to be used directly for activities in collaborating labs at another California institution (presumably via a subcontract), but an applicant should describe the proposed policies for assignment and use of such funds. For example, one might decide that some collaborative funds could be provided for activities in a collaborator's lab for which there is no other source of support if the project was sufficiently compelling. We would imagine that some projects would have no significant outside costs (e.g. generation of samples as part of another project and paid for from another grant) whereas some other projects (e.g. perhaps one from a smaller lab with more limited resources) might require funds to pay for supplies or technical services. CIRM's goal is to see the Centers support the most promising and transformative stem cell genomics projects and provide access to cutting-edge genomics technology for California stem cell researchers.

Can an application include a partner PI from another country?

The Genomics Centers RFA has no provision for Partner PI's and will not have participation of our Collaborative Funding Partners. We are asking applicants to describe how they will promote interaction and/or data sharing with other genomics centers outside of California, and we hope that productive alliances with international groups will develop after the CIRM Centers are established.

- The RFA requires that collaborative research projects comprise 30% of the Genomic Center activities, research, and budget.
  - a. May the 30% include intra-mural collaborative research?
  - b. If so, is there a limit to the 30% collaboration requirement that could be consumed by intramural projects?

For the first part, yes, collaborative projects could be with investigators at the same institution that receives the Center Award (although the investigators should not the PD or a Co-PD on the award). However, such projects would have to go through the same assessment and selection process as that used for outside projects, and appropriate COI policies and procedures must be followed. The RFA contains a provision for the establishment of a collaborative resource committee, which is essentially responsible for development of requests for proposals, solicitation and receipt of applications, for putting in place the COI policy, and for their review and their final acceptance. The composition of that committee which is responsible for the implementation and management of collaborative resources should have the majority of its membership from institutions that are independent of the grantee organization. The grantee organization here not only refers to the program director's organization but to the co-program director's organization. This system provides a check and balance, as part of the goal of the collaborative project program is to allow access for California stem cell researchers to genomics resources and technology to which they might not otherwise have access.

For the second part of the question: we have placed no limit. A discussion of the policies and procedures that you would put in place for establishing a collaborative research program should be part of your proposal. CIRM will look at the recommendations of the project, and there will be reporting twice a year on this program including reporting on projects that are funded through the collaborative projects part of the program.

 We understand that there will be only one genomics center funded for Data Coordination and Management. Is this part of the grant optional or must each applicant include a proposal for Data Coordination and Management, knowing only one genomics center will be awarded this component?

Each applicant must include a proposal for Data Coordination and Management.

• Ten percent of direct project costs may be used to purchase equipment. May we use the 10% to budget for purchase of sequencing instruments?

Yes, but all equipment requests need to be justified. There is a lot of sequencing capacity within the state of California already, so a compelling justification will be important. Equipment that is intended to

broadly support program activity, i.e., not just the center-initiated projects but also the collaborative research projects, should be budgeted as part of the Center organization and operations. Equipment associated with more specific projects should be budgeted in the context of that project.

What is the expected quality of sequence data produced by the Center?

That will be something that will be addressed by the reviewers. If you propose a sequencing component, please refer to standards in place for large sequencing projects such as those at the NIH-funded DNA sequencing centers. As applicant or co-applicant organizations must have established genomics facilities in California with expertise and capability in second-generation sequencing, bioinformatics and genomics data analysis and associated technology, there is an expectation that applicants will propose and describe sequencing standards that are appropriate to proposed activities and acceptable to expert reviewers.

• We have a lot of interest about the collaborative projects. Should we provide a list of proposed projects or letters from other investigators?

We have not specifically requested that people list collaborative projects. As this is a five year award, there is an expectation that some funds for collaborative projects would be reserved until later years of the grant, and the nature of those projects is difficult to predict. The key information you should include about the collaborative research is descriptions of what type of projects you are interested in, how would you evaluate them and how they would be carried out once approved. Having said that, if there are specific projects that you have in mind, it would be helpful for reviewers to get a broad sense of the scope and type of collaborations and/or projects you are talking about. You also should provide an idea of the duration and funds you will make available for individual collaborative projects. So a brief discussion of potential collaborative projects would be helpful, but letters are not required. All collaborations will have to be approved through a review process proposed by the applicant and vetted through our review process.

• Should the applicant or the Center provide a formal training in genomics as part of the Center or CIRM supported activities?

No. The role of the Center is to act as the expert in these areas and provide advice and resources to California scientist. Training is not a component of this award.

Should this be a translational-focused Center or more basic-focused?

We're not requiring a specific focus. We can certainly see in a context of Center-initiated projects that they could be either more basic or more translational, depending on the nature of the project and collaborative research. Both activities are desirable. Note that there is a focus on human cell and tissue research.

For collaborative projects – should they be big or small?

This is a situation where we are asking you to propose your policy based on your knowledge of the types of programs that may utilize genomics resources. There may be large projects, small projects, or a combination of both. We are asking you to give us a sense of the collaborative research program that you would put in place.

Where does one request Center director's salary?

The Center director's salary could be in Center operations and administration, but we would expect the Center director to not just be the administrative head of the program but also likely to be involved in the collaborative research program and/or one of the Center-initiated projects. We have requested, that the Center director commit 25% of his or her time to the program, and of that 25% can be divided between overall Center administrative as well as specific activities in which the person would be involved in, and the salary would follow the percent effort.

 What would be the minimum amount of time that a Center director would have to commit to running a Center?

As described in the RFA, 25% for the program director and 15% for the co-program director is the minimum commitment to the program, not just Center administrative activities. We have specifically stated that the co-program director must have responsibilities for a distinct program component or activities and have a clearly defined role in the overall program. That is true for the program director as well.

Will co-program directors have to be named at the time of the LOI.

As specified in the RFA, the program director and co-program director named in the application must be the same as that listed in the LOI, otherwise the application may be deemed in eligible.

Can funding be spent on both program director and co-program director's salaries?

Yes, subject to our requirements that both program director and co-program directors must have a position in a California institution and will be paid in the context of that.

Are salaries for administrative staff allowed?

Yes and no. Yes in the sense that insofar as the program director devotes part of his or her time to the overall administration of the program. Yes, insofar as we have allowed for a Center project manager, or coordinator, or program administrator to be budgeted as a direct expense with adequate justification. No, in the sense of administrative assistants or other comparable positions that would be involved in the administration of the award are considered part of indirect costs.

If there are two co-program directors does each have to commit to 15 percent time?

Yes. The expectation is that each co-program director would commit 15% time, and there is an expectation that if a co-program director is named, they will have a responsibility for a distinct program component.

 Is it possible that two Centers would be created in Northern California or two in Southern California?

Although it is formally possible that there would be two Centers either in the southern or northern location that might be a programmatic consideration by both the grants working group and the ICOC.

Will a Center being comprised of different institution provide an advantage?

In the context of the RFA it depends on what resources are available within your own institution. We state in the eligibility criteria that applicants with or without co-applicants must have an established genomics facility in California with expertise and capability in sequencing, bioinformatics, genomic data analysis and associated technology. If you have all of those components within your institution, you could be very competitive on your own. If you don't, it might make sense to form collaborations with other institutions that bring those capabilities.

• Is there an expectation of the CIRM Center working with the bio bank for characterization of the ES and IPS line?

No. There is not necessarily that expectation. The CIRM iPSC Initiative is a two to four year program with the different elements of that program (tissue collection, derivation, and banking) expected to take place over two to four years. Whereas one of the potential collaborative projects might focus on these iPSC lines, it certainly would not be one of the early projects. There could be potential for characterization of those lines to be part of a Center-initiated project which would start later in the grant period.

 How would you rate new technologies like single cell genomics versus more established methods?

This is a question for reviewers, but keep in mind what we're really trying to do with the award. It is supposed to establish one or two Centers of Excellence in California dedicated to the application cutting edge genomic approaches to substantive problems of human stem cell biology. The Center-initiated projects can include both genomics research projects that are likely to result in extensive data collection and analysis and innovative technology development projects to address major bottlenecks in stem cell genomic research, including information technology and data analysis. The idea is to be on the cutting edge of technology and resources to be made available for California stem cells researchers.

• Do we want a hands on component for post-doc, etc., like a place with equipment and expertise for onsite collaboration.

It is up to the applicant to propose how to best configure resources to meet the goals of the Center in terms of access to California stem cell scientists; that might fall under the operational and organizational plan.

• Is there a preference for projects featuring hESCs over those using hiPSCs or adult stem cells.

There are not explicit preferences in the RFA. Reviewers will consider this in the context of the Center initiated projects being proposed. We have no bias one way or the other. For the two to four project that will be proposed in these applications, each Center-initiated project will be judged as a distinct research project. Applicants are expected to make a case for the merits of their projects.

What kind of resources do you anticipate a successful applicant will spend their money on?
 There are already significant resources throughout the state for next generation sequencing.

You may want to consider that you would handle sequencing through a sub-contractor. Perhaps you have arranged for a collaborator who has that expertise. It is a matter of you deciding how you are going to cover the needs of the genomics Center.

Are epigenetic analysis projects within the scope of this RFA?

Yes, we use the term genomic to include epigenomics. But it is important to note that this is a stem cell genomics program. Not just stem cell biology and its applications but <u>human</u> stem cell biology and its applications.

• It says that there will be a large demand for these resources. When you say resources in this context it is the collaborative resources. How will the collaborative funds be allocated and will scientists outside the Centers have access to the platform?

The collaborative research part of the program is a very critical part of the program, and Centers must develop policies and establish procedures that promote collaboration and make the genomic resources within the Center available to California stem cell researchers. Applicants will be reviewed on how the proposal addresses the collaborative process including how collaborative projects will be defined, developed and evaluated by the Center collaborative resources committee. Reviewers will also focus on how conflicts of interest will be handled, review criteria to be used for evaluation of collaborative proposals and how you will manage projects after they have been approved.

Do we expect the Centers to be sustainable after the term of the grant?

We hope that the expertise and associated intellectual hardware and software, infrastructure that has been developed over the five-year term of this award would be an asset to attract continual operational support. There is nothing in this RFA that requires this, and it is not a review criterion.

How many collaborations will the Centers support?

We are asking the centers to describe how they will define and develop solicitations and proposals as well as the numbers and scope of collaborative projects to be under taken.

How can we insure that the applicants will possess the skills and capacity to engage in all of the
activities needed for the Centers to function effectively?

That is what the applications are about and why we have reviewers. We try to put forth review criteria and have requested information that would address that. That is why we have said that you are

welcome to designate two co-program directors to ensure that all the key functions of the genomics center will be represented in your application.

• Will finalist be site visited?

Finalist will not be site visited; however successful (funded) applicants will be site visited on an annual basis.

Can one informatics group be part of more than one center proposal?

Yes. Within the context of the RFA we are requiring all applications to include a section addressing data coordination and management, but only one award will include that component.